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ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/646,569	SPECHT ET AL.	
	Examiner	Art Unit	
	Cynthia B. Wilder, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *28-30,37 and 2025* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19,26,27 and 31-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-19, 26, 27, 31, 32-37 and SEQ ID NO: 60 filed on 3/12/2004 is acknowledged. The traversal is on the ground(s) that that the examiner has not established that an undue searching burden would be involved in examining the full scope of the unitary subject matter of the claims of this application. Applicant request that the restriction requirement be withdrawn. This is not found persuasive because the inventions of Groups I-IV do not recite the same or corresponds to a "special technical feature linking the recited groups, as would be necessary to fulfill the requirements for unity of invention. Likewise the broadest invention, namely the product claims 1-3, 5-10, 15, 31, 32, 36 and 37 include fragments or variant sequences or complement sequences of claimed nucleic acid sequences. Accordingly, the claims are sufficiently broad so as to encompass nucleic acid fragments taught in the art (e.g., see, Jacobs et al, (US Patent 5965397, teaching fragments of the nucleic acid sequence of SEQ ID NO: 60). As the product of Group I does not represent a contribution over the prior art, the claims lack a special technical feature that is the same or that corresponds to a special technical feature of the other claimed inventions. Additionally, the different Groups 1-IV are distinct one from the other because the inventions of Groups I-IV comprises multiple distinct products, such as e.g., nucleic acids, antibodies, polypeptides, and pharmaceutical reagents, that are structurally, functionally and chemically distinct one from the other as indicated in the prior Office action. A search of the different invention are not co-extensive and would require an

undue search burden to the Examiner because it would require a search of non-overlapping subject matters. Thus, requirement is still deemed proper and is therefore made FINAL.

Status of Claims

2. Claims 1-37 and SEQ ID NOS: 1-209 are pending. Claims 20-25, 28-30, 37 and SEQ ID NOS: 1-59, 61-209 have been withdrawn from consideration as being drawn to a non-elected invention. Claims 1-19, 26, 27, 31, 32-36 and SEQ ID NO: 60 are addressed in this Office Action.

Objections

3. The following objections are made because of these minor informalities:

(a) The disclosure at pages 3-4, 6-8, 14, 16, 101, 118 and Table II and claims 1-4, 26, 27, 33 are objected to because the designation for the sequence identifier is improper (see MPEP§ 2422.03). It is suggested amending the disclosure and claims to recite --SEQ ID NO:--.

(b) The disclosure at pages 99-100 is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

Claim Rejections - 35 USC § 101 (Lack of Utility)

4. The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Application under 35 U.S.C. 112,

first paragraph, "Written Description" requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility:

> Credible Utility" - Where an Applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by Office personnel as being "wrong". Rather, Office personnel must determine if the assertion of utility is credible (i.e., whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided). An assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (b) the facts upon which the assertion is based is inconsistent with the logic underlying the assertion. Credibility as used in this context refers to the reliability of the statement based on the logic and facts that are offered by the Applicant to support the assertion of utility. A *credible* utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use. For example, no perpetual motion machines would be considered to be currently available. However, nucleic acids could be used as probes, chromosome markers, or forensic or diagnostic markers. Therefore, the credibility of such an assertion would not be questioned, although such a use might fail the *specific* and *substantial* tests (see below).
>
> "Specific Utility" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.
>
> "Substantial utility" - a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.
>
> "Well established utility" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. "Well established utility" does not encompass any "throw away" utility that one can dream up for an invention or a nonspecific utility that would apply to virtually every member of a general class of materials, such as proteins or DNA.

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-19, 26, 27, 31-36 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

The claimed nucleic acid sequence that codes a gene product or a part thereof, comprising a) a nucleic acid sequence of SEQ ID NO: 60; b) an allelic variation of the nucleic acid sequences named under a); or c) a nucleic acid sequence that is complementary to the nucleic acid sequence named under a) or b), expression, vector, host cells, clones and methods of using the claimed nucleic acid sequence to produce full-length genes, as a vehicle for gene transfer, as a tool for finding active ingredients against breast cancer or use in sense or antisense form is not supported by a specific asserted utility because the disclosed use of the isolated nucleic acid molecule is not specific and is generally applicable to any nucleic acid. Specifically, the specification provides no support for a specific, asserted or substantial utility for the named invention. For example, the specification states at page 5 that the nucleic acid fragments according to the invention can be used to produce full-length genes. The specification states that the genes that can be obtained are likewise the subject matter of this invention. At page 11 in Example 1, the specification discloses the search for expressed sequence tags that corresponds to tumor-related candidate genes. At page 13 Example 2, the specification discloses algorithm for identification and lengthening of partial cDNA sequences with altered expression pattern, electronic northern to disclose the frequency of a nucleic acid

disclosed herein in normal tissue versus tumor tissue. At page 97, in Example 3, the specification discloses automatic lengthening of the partial sequence. At page 99 in Example 4, the specification discloses mapping of nucleic acid sequences on the human genome. At page 100, in Example 5, the specification teaches obtaining genomic DNA sequence from BAC libraries. Nowhere in the specification is there specific, asserted or credible utility for the claimed nucleic acid sequence or the encoded protein. The specification *only speculates* that the claimed invention may be used to produce the full-length genes, as a vehicle for gene transfer, in sense or antisense form or used for expression of polypeptides that can be used as tools for finding active ingredients against breast cancer. These are all non-specific uses that are applicable to nucleic acids and proteins in general and not particular or specific to the nucleic acids or protein being claimed. Likewise, the instant application does not disclose a connection between presence or expression of SEQ ID NO: 60 and breast cancer. The specification does not by any means show such nexus. The demonstration of expression of a sequence in a specific tissue type cannot be translated to mean that that sequence is necessarily a marker for cancer in that tissue. In addition, the application does not disclose or teach the meaning or significance of any particular assay for expression of SEQ ID NO: 60.

The claimed invention is not supported by a substantial utility because no substantial utility has been established for the claimed isolated nucleic acid molecule or the encoded protein, or a portion thereof or the products formed. For example, a nucleic acid may be utilized to obtain a protein. The protein could then be used in conducting research to functionally characterize the protein. The need for such research clearly

indicates that the protein and/or its function is not disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this, the protein that is be produced as final products resulting from processes involving claimed nucleic acid does not have any asserted or identified specific and substantial utilities. The research contemplated by Applicant to characterize potential protein products, especially their biological activities, does not constitute a specific and substantial utility. Identifying and studying the properties of the nucleic acid or the protein itself or the mechanisms in which the protein is involved does not define a "real world" context or use. Similarly, the claimed uses of the instant specification as a diagnostic tool for breast cancer or use in antisense or sense form or use in vehicles for gene transfer is neither substantial nor specific due to being generic in nature and applicable to a myriad of nucleic molecules as noted by the plethora of nucleic acid molecules denoted by SEQ ID NOS: 1-76 and 161-178. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the nucleic acid encoding the isolated nucleic acid molecule of SEQ ID NO: 60 such that another non-asserted utility would be well established for the composition.

Claims 1-19, 26, 27, 31-36 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and

substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Claim Rejections - 35 USC § 101 (Non-statutory subject matter)

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1-3, 5-10, 15, 31-33 and 36 are rejected under 35 U.S.C. 101 because the claimed invention is directed to a non-statutory subject matter. Claims 1-3, 5-10, 15, 31-33 are drawn to a nucleic acid sequence or DNA fragment, which reads on a product of nature. The claims should be amended to indicate the hand of the inventor, for example, the insertion of "isolated" in connection with the nucleic acid sequence and DNA fragment to identify a product not found in nature (See MPEP 2105).

Claim Rejections - 35 USC § 112 second Paragraph/ 35 USC § 101 (Use claims)

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 14, 26, 27, 34 and 35 provide for the use of a nucleic acid sequence or genomic genes, but, since the claim does not set forth any steps involved in the

method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

10. Claims 14, 26, 27, 34 and 35 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 11: (Lack of Adequate Written Description)

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1-19, 26, 27, 31-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is drawn to nucleic acid sequence that codes a gene product or a part thereof, a) comprising a nucleic acid sequence of SEQ ID NO: 60; b) an allelic variation of the nucleic acid sequences named under a); or c) a nucleic acid

sequence that is complementary to the nucleic acid sequence named under a) or b), expression, vector, host cells, clones and methods of using the claimed nucleic acid sequence to produce full-length genes, or as a tool for finding active ingredients against breast cancer or use in sense or antisense form. The specification discloses that the claimed nucleic acid sequences are human nucleic acid sequences from breast tissue, which codes for gene products or parts thereof, their functional genes that code at least one bioactive polypeptide and their use. Specification teaches that the claimed nucleic acid sequences encompasses DNA fragments, portions are parts thereof of the sequences from SEQ ID NOS: 1-76 and 161-178, especially SEQ Id NO: 60, genomic genes, sequences that hybridize to SEQ ID NO: 60, mutated sequences, allelic variants, splice variants, sequences that have a recited degree of identity or similarity or homology to SEQ ID NO: 60, and so forth. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

The skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v.

Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an Applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.
>
> The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, none of the sequences encompassed by the claims 1-1-19, 26, 27, and 31-36 meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed is not a representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is separable from its enablement provision. (See page 1115.)

Claim Rejections - 35 USC § 112

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claim 7 is vague and indefinite overall because it is unclear as to what "portions of the nucleic acid molecule of SEQ ID NO: 60" or what "amount" is considered "sufficient" to for the hybridization reaction to occur. Likewise, the specification does not define or describe any conditions for hybridization. Therefore, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention as it relates to recited claim.

Conclusion

15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone

number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to cynthia.wilder@uspto.gov. Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Wilder

CYNTHIA WILDER
PATENT EXAMINER

5/17/2004